

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kotewicz *et al.*

Appl. No. 10/024,149

Filed: December 21, 2001

For: **Cloned Genes Encoding Reverse  
Transcriptase Lacking RNase H  
Activity**

Confirmation No. 4033

Art Unit: 1652

Examiner: *To Be Assigned*

Atty. Docket: 0942.049000A/RWE/MTT

**Sixth Supplemental Information Disclosure Statement**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Sixth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Fifth Information Disclosure Statement filed herewith in connection with the above-captioned application. All documents were cited by or submitted to the Office in Application No. 09/220,330, filed December 24, 1998.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search

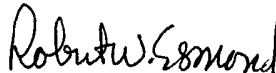
has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Sixth Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. Thus, no statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: March 5, 2003

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>53</u>	Barr, P.J., et al., "Expression of Active Human Immunodeficiency Virus Reverse Transcriptase in <i>Saccharomyces Cerevisiae</i> ," <i>Bio/Technology</i> 5:486-489, Nature Publishing Company (May 1987).
AS	<u>53</u>	Bathurst, I.C., et al., "Characterization of the Human Immunodeficiency Virus Type-1 Reverse Transcriptase Enzyme Produced in Yeast," <i>Biochem. Biophys. Res. Commun.</i> 171:589-595, Academic Press, Inc. (1990).
AT	<u>53</u>	Champoux, J.J., "Roles of Ribonuclease H in Reverse Transcription," in <i>Reverse Transcriptase</i> , Ch. 6, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 103-117 (1993).

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	AR	<u>54</u>	Farmerie, W.G., et al., "Expression and Processing of the AIDS Virus Reverse Transcriptase in <i>Escherichia coli</i> ," <i>Science</i> 236:305-308, Association for the Advancement of Science (1987).
	AS	<u>54</u>	Georgiadis, M., et al., "Mechanistic implications from the structure of a catalytic fragment of Moloney murine leukemia virus reverse transcriptase," <i>Structure</i> 3:879-892, Current Biology LTD., (1995).
	AT	<u>54</u>	Golomb, M. and Grandgenett, D.P., "Endonuclease Activity of Purified RNA-directed DNA Polymerase from Avian Myeloblastosis Virus," <i>J. Biol. Chem.</i> 254:1606-1613, American Society of Biological Chemists, Inc., (1979).

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	AR	<u>55</u>	Hansen, J., et al., "RNase H Activity Associated with Bacterially Expressed Reverse Transcriptase of Human T-cell Lymphotropic Virus III/Lymphadenopathy-associated Virus," <i>J. Biol. Chem.</i> 262:12393-12396, American Society for Biochemistry and Molecular Biology, (1987).
	AS	<u>55</u>	Hansen, J., et al., "Identification and characterization of HIV-specific RNase H by monoclonal antibody," <i>EMBO J.</i> 7:239-243, IRL Press Limited (1988).
	AT	<u>55</u>	Houts, G.E., et al., "Reverse Transcriptase from Avian Myeloblastosis Virus," <i>J. Virol.</i> 29:517-522, American Society for Microbiology (1979).

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	AR	<u>56</u>	Huber, H.E., et al., "Human Immunodeficiency Virus 1 Reverse Transcriptase," <i>J. Biol. Chem.</i> 264:4669-4678, American Society for Biochemistry and Molecular Biology, Inc. (1989).
	AS	<u>56</u>	Inouye, S., and Inouye, M., "Bacterial Reverse Transcriptase," in <i>Reverse Transcriptase</i> , Ch. 17, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 391-410 (1993).
	AT	<u>56</u>	Kacian, D.L. and Myers, J.C., "Synthesis of extensive, possibly complete, DNA copies of poliovirus RNA in high yields and at high specific activities," <i>Proc. Natl. Acad. Sci. USA</i> 73:2191-2195, National Academy of Sciences USA (1976).

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	AR	<u>57</u>	Larder, B., et al., "Site-Specific mutagenesis of AIDS virus reverse transcriptase," Nature 327:716-717, Macmillan Publishers Ltd. (1987).
	AS	<u>57</u>	Larder, B., et al., "AIDS virus reverse transcriptase defined by high level expression in <i>Escherichia coli</i> ," EMBO J. 6:3133-3137, IRL Press Limited (1987).
	AT	<u>57</u>	Le Grice, S., "Human Immunodeficiency Virus Reverse Transcriptase," in Reverse Transcriptase, Skalka, A.M. and Goff, S.P., eds., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 163-191 (1993).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>58</u>	Levin, J.G., et al., "Functional Organization of the Murine Leukemia Virus Reverse Transcriptase: Characterization of a Bacterially Expressed AKR DNA Polymerase Deficient in RNase H Activity," <i>J. Virol.</i> 62:4376-4380, American Society for Microbiology (1988).
	AS	<u>58</u>	Lightfoote, M.M., et al., "Structural Characterization of Reverse Transcriptase and Endonuclease Polypeptides of the Acquired Immunodeficiency Syndrome Retrovirus," <i>J. Virol.</i> 60:771-775, American Society for Microbiology (1986).
	AT	<u>58</u>	Lori, F., et al., "Enzymatically Active Forms of Reverse Transcriptase of the Human Immunodeficiency Virus," <i>AIDS Res. Hum. Retroviruses</i> 4:393-398, Mary Ann Leibert, Inc., Publishers (1988).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>59</u>	Lowe, D.M., et al., "HIV-1 Reverse Transcriptase: Crystallization and Analysis of Domain Structure by Limited Proteolysis," <i>Biochemistry</i> 27:8884-8889, American Chemical Society (1988).
	AS	<u>59</u>	Mizrahi, V., et al., "Mutagenesis of the Conserved Aspartic Acid 443, Glutamic Acid 478, Asparagine 494, and Aspartic Acid 498 Residues in the Ribonuclease H Domain of p66/p51 Human Immunodeficiency Virus Type 1 Reverse Transcriptase," <i>J. Biol. Chem.</i> 269:19245-19249, American Society for Biochemistry and Molecular Biology, Inc. (1994).
	AT	<u>59</u>	Müller, B., et al., "Co-expression of the Subunits of the Heterodimer of HIV-1 Reverse Transcriptase in <i>Escherichia coli</i> ," <i>J. Biol. Chem.</i> 264:13975-13978, American Society for Biochemistry and Molecular Biology, Inc. (1989).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	<u>60</u>	Myers, J.C., et al., "Synthesis of full-length DNA copies of avian myeloblastosis virus RNA in high yields," <i>Proc. Natl. Acad. Sci. USA</i> 74:2840-2843, National Academy of Sciences USA (1977).
	AS	<u>60</u>	Myers, J.C., et al., RNA primer used in synthesis of anticomplementary DNA by reverse transcriptase of avian myeloblastosis virus," <i>Proc. Natl. Acad. Sci. USA</i> 77:1316-1320, National Academy of Sciences USA (1980).
	AT	<u>60</u>	Najmudin, S., et al., "Crystal Structures of an N-terminal Fragment from Moloney Murine Leukemia Virus Reverse Transcriptase Complexed with Nucleic Acid: Functional Implications for Template-primer Binding to the Fingers Domain," <i>J. Mol. Biol.</i> 296:613-632, Academic Press, Inc. (2000).

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	AR	<u>61</u>	Prasad, V.R., "Genetic Analysis of Retroviral Reverse Transcriptase Structure and Function," in <i>Reverse Transcriptase</i> , Skalka, A.M. and Goff, S.P., eds., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 135-162 (1993).
	AS	<u>61</u>	Reardon, J., et al., "Human Immunodeficiency Virus Reverse Transcriptase," <i>J. Biol. Chem.</i> 266:14128-14134, American Society for Biochemistry and Molecular Biology, Inc. (1991).
	AT	<u>61</u>	Schatz, O., et al., "HIV-1 RT-associated ribonuclease H displays both endonuclease and 3' → 5' exonuclease activity," <i>EMBO J.</i> 9:1171-1176, IRL Press Limited (1990).

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AR	<u>62</u>	Schiff, R.D. and Grandgenett, D.P., "Virus-Coded Origin of a 32,000-Dalton Protein from Avian Retrovirus Cores: Structural Relatedness of p32 and the $\beta$ Polypeptide of the Avian Retrovirus DNA Polymerase," <i>J. Virol.</i> 28:279-291, American Society for Microbiology (1978).
AS	<u>62</u>	Skalka, A.M., "Endonuclease Activity Associated with Reverse Transcriptase of Avian Sarcoma-Leukosis Viruses," in <i>Reverse Transcriptase</i> , Ch. 10, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, pp. 193-204 (1993).
AT	<u>62</u>	Srivastava, A. and Modak, M.J., "Reverse Transcriptase-Associated RNase H. Part IV. Pyrophosphate does not inhibit RNase activity of AMV DNA polymerase," <i>Biochem. Biophys. Res. Commun.</i> 91:892-899, Academic Press, Inc. (1979).

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	AR	<u>63</u>	Starnes, M.C., et al., "Enzyme Activity Gel Analysis of Human Immunodeficiency Virus Reverse Transcriptase," <i>J. Biol. Chem.</i> 263:5132-5134, American Society for Biochemistry and Molecular Biology, Inc. (1988).
	AS	<u>63</u>	Takatsuji, H., et al., "Expression of cauliflower mosaic virus reverse transcriptase in yeast," <i>Nature</i> 319:240-243, Macmillan Publishers Ltd. (1986).
	AT	<u>63</u>	Tanese, N., et al., "Expression of Reverse Transcriptase Activity of Human T-Lymphotropic Virus Type III (HTLV-III/LAV) in <i>Escherichia coli</i> ," <i>J. Virol.</i> 59:743-745, American Society for Microbiology (1986).

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	AR	64	Thimmig, R.L. and McHenry, C.S., "Human Immunodeficiency Virus Reverse Transcriptase," <i>J. Biol. Chem.</i> 268:16528-16536, American Society for Biochemistry and Molecular Biology, Inc. (1993).
	AS	64	Tisdale, M., et al., "Characterization of Human Immunodeficiency Virus Type 1 Reverse Transcriptase by Using Monoclonal Antibodies: Role of the C Terminus in Antibody Reactivity and Enzyme Function," <i>J. Virol.</i> 62:3662-3667, American Society for Microbiology (1988).
	AT	64	Tisdale, M., et al., "Structural characterization of HIV reverse transcriptase: A target for the design of specific virus inhibitors," <i>J. Antimicrobiol. Chemother.</i> 23(Suppl A):47-54, Academic Press, Inc. (1989).

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AR	65	Van Beveren, C. and Goulian, M., "Optimal Conditions for Synthesis of Long Complementary DNA Product with Moloney Murine Leukemia Virus," <i>J. Virol.</i> 30:951-954, American Society for Microbiology (1979).	
AS	65	Veronese, F., et al., "Characterization of Highly Immunogenic p66/p51 as the Reverse Transcriptase of HTLV-III/LAV," <i>Science</i> 231:1289-1291, Association for the Advancement of Science (1986).	
AT	65	Volkman, S., et al., "Enzymatic Analysis of Two HIV-1 Reverse Transcriptase Mutants with Mutations in Carboxyl-terminal Amino Acid Residues Conserved among Retroviral Ribonucleases H," <i>J. Biol. Chem.</i> 268:2674-2683, American Society for Biochemistry and Molecular Biology, Inc. (1993).	

EXAMINER	DATE CONSIDERED
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 0942.049000A/RWE/MTT	APPLICATION NO. 10/024,149
	APPLICANTS Kotewicz <i>et al.</i>	
	FILING DATE December 21, 2001	GROUP 1652

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
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	AH						
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	AJ						
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>66</u>	Wöhrl, B.M., et al., "Kinetic Analysis of Four HIV-1 Reverse Transcriptase Enzymes Mutated in the Primer Grip Region of p66," <i>J. Biol. Chem.</i> 272:17581-17587, American Society for Biochemistry and Molecular Biology, Inc. (1997).
AS	<u>66</u>	"Complaint," dated June 29, 2000, from <i>Life Technologies, Inc. v. Promega Corporation</i> , U.S. District Court, Western District of Wisconsin, Civil Action No. 00C 0407 C.
AT	<u>66</u>	"Answer," dated October 17, 2000, from <i>Life Technologies, Inc. v. Promega Corporation</i> , U.S. District Court, Western District of Wisconsin, Civil Case No. 00-C-0407-C.

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	67	"Complaint," dated June 29, 2000, from Life Technologies, Inc. v. Stratagene Holding Corp., Stratagene, Inc., and Biocrest Manufacturing, L.P., U.S. District Court, District of Delaware, Civil Action No. 00-620.
	AS	67	"Answer," dated November 30, 2000, from Life Technologies, Inc. v. Stratagene Holding Corp., Stratagene, Inc., and Biocrest Manufacturing, L.P., U.S. District Court, District of Delaware, Civil Action No. 00-620.
	AT		

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